UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,233	02/06/2006	**Wusi C. Maki**	814.0035	2576

29085 7590 11/20/2009

HOWARD EISENBERG, ESQ.
1220 LIMBERLOST LANE
GLADWYNE, PA 19035

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
11/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,233	MAKI ET AL.	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-122* is/are pending in the application.

4a) Of the above claim(s) *101,104,106,107,110,113,114 and 116* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96,97,99,100,102,103,105,108,109,111,112,115 and 117-122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 96, 97 and 99-122, in the reply filed on 22 October 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant also elected the following species: Group A: claim 100; Group B: claim 103; Group C: claim 108; group D: claim 111; and group E: claims 112 and 115.

Claims 98, 101, 104, 106, 107, 110, 113, 114 and 116 are withdrawn as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 96, 97, 100, 102, 103, 105, 108, 112, 115, 117-119, 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US 5,665,539) in view of Tyvoll et al. (US 2004/0086870).

Sano et al. teach a method comprising:

immobilizing the target in a reaction vessel (target antigen is immobilized onto the surface of microtiter plate well, col. 3, lines 49-53);

contacting the target with a signal probe, wherein the signal probe comprising a recognition component and a signal template component, wherein the recognition component specifically binds directly to the target and the signal template codes for a signal molecule (col. 3, lines 1-13);

producing the signal molecule using the signal template component coding for the signal molecule (col. 3, lines 7-13); and

detecting the signal molecule at a detection surface (PCR products are detected at a surface using gel electrophoresis, col. 4, lines 7-16) and indicates the presence of the target in the sample (col. 4, lines 15-16).

Sano et al. differ from the instant claims by failing to teach the signal molecule comprising a recognition head and an electrically charged tail and detecting the detection surface comprising an affinity binding molecule, wherein the recognition head of the signal molecule binds to the affinity binding molecule and the electronically charged tail of the signal molecule brings a charge to the detection surface that is detected.

Tyvoll et al. teach a nucleic acid molecule comprising a recognition head and an electrically charged tail (target is nucleic acid and binds to receptor therefore has a recognition head, par. 84; assay receptor may be the same as the preselection receptor, par. 31; preselection receptor may be substantially shorter than the target, par. 50; therefore the target has an excess nucleic acid strand that is not bound to the assay receptor which is a tail, since nucleic acids are negatively charged, the nucleic acid molecule has an electrically charged tail) that are immobilized to a detection surface comprising an affinity binding molecule (receptor is affinity binding molecule and is disposed in an array at defined positions, par. 84), wherein the recognition head of the nucleic acid molecule binds to the affinity binding molecule (target binds to receptor therefore nucleic acid molecule binds to affinity binding molecule, par. 84), and the electrically charged tail of the signal molecule is detected by bringing a charge to the detection surface (electrical signal is measured as nucleic acid duplex is formed, par. 142; target nucleic acid has a tail that is negatively charged and therefore brings excess charge to the detection surface), in order to provide genetic screening that is rapid and relatively low cost. Tyvoll et al. teach detection by optical signal, capillary electrophoresis or electrical signal (par. 84 and 142).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the signal molecule in the invention of Sano et al., in an electrical detection method, wherein the nucleic acid has a recognition head and an electrically charged tail and a detection surface comprising an affinity binding molecule that is substantially shorter than the nucleic acid, wherein the recognition head

of the signal molecule specifically binds to the affinity binding molecule and the electrically charged tail of the signal molecule brings a charge to the detection surface that is detected as taught by Tyvoll et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection technique and since only the same expected nucleic acid detection would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

With respect to claim 97, Sano et al. teach washing to remove any signal probe that is not specifically bound to the target immobilized in the reaction vessel (col. 8, lines 8-44).

With respect to claims 112 and 115, Sano et al. teach the signal molecule comprising an RNA transcript (marker may be RNA and therefore the signal molecule comprises an RNA transcript, col. 5, lines 10-20) and Tyvoll et al. teach the nucleic acid having an RNA aptamer that specifically binds to the affinity binding molecule (DNA or RNA may be used, par. 83 and 90; and sequence binds to affinity binding molecule, par. 104).

Regarding claims 100, 102, 103, 105 and 108, Tyvoll et al. teach the recognition component binding directly to the target (par. 84) and the affinity binding molecule immobilized directly on the detection surface (par. 84), wherein the affinity binding molecule is a nucleic acid (par. 84).

With respect to claims 117 and 119, Tyvoll et al. teach the entire target being a nucleic acid, therefore the recognition component and the electrically charged tail are nucleic acids (par. 84).

Regarding claim 118, Sano et al. teach the target being a nucleic acid (col. 3, line 49-col. 4, line 16).

With respect to claims 121 and 122, Tyvoll et al. teach the detection surface (assay substrate) being a semiconductor material that is silicon (par. 61).

3. Claims 96, 97, 100, 102, 103, 105, 108, 112, 115, 117-119, 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US 5,665,539) in view of Eggers et al. (US 5,532,128).

Sano et al. teach a method comprising:

immobilizing the target in a reaction vessel (target antigen is immobilized onto the surface of microtiter plate well, col. 3, lines 49-53);

contacting the target with a signal probe, wherein the signal probe comprising a recognition component and a signal template component, wherein the recognition component specifically binds directly to the target and the signal template codes for a signal molecule (col. 3, lines 1-13);

producing the signal molecule using the signal template component coding for the signal molecule (col. 3, lines 7-13); and

detecting the signal molecule at a detection surface (PCR products are detected at a surface using gel electrophoresis, col. 4, lines 7-16) and indicates the presence of the target in the sample (col. 4, lines 15-16).

Sano et al. differ from the instant claims by failing to teach the signal molecule comprising a recognition head and an electrically charged tail and detecting the detection surface comprising an affinity binding molecule, wherein the recognition head of the signal molecule binds to the affinity binding molecule and the electronically charged tail of the signal molecule brings a charge to the detection surface that is detected.

Eggers et al. teach electric detection of binding of nucleic acid molecules (col. 3, lines 4-10), wherein the nucleic acid molecule comprises a recognition head and an electrically charged tail target nucleic acid, 28, has head that is bound to receptor, 26, and tail that is not bound to receptor, above 28, Fig. 4, col. 4, line 61-col. 5, line 3; longer DNA ligand is washed onto the surface to hybridize with complementary DNA probes, col. 7, lines 40-53) and a receptor nucleic acid molecule is an affinity binding molecule and is immobilized to a detection surface (col. 7, lines 47-48), wherein the target nucleic acid binds to the affinity binding molecule (target nucleic acid, 28, has head that is bound to receptor, 26, and tail that is not bound to receptor, above 28, Fig. 4, col. 4, line 61-col. 5, line 3), and the electrically charged tail of the nucleic acid molecule is detected by bringing a charge to the detection surface (nucleic acid molecule is a charged molecule and is brought to the surface and electrical properties are measured for detection, col. 7, lines 51-53), in order to simultaneously detect multiple molecular structures.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the signal molecule in the invention of Sano et al.,

in an electrical detection method, wherein the nucleic acid has a recognition head and an electrically charged tail and a detection surface comprising an affinity binding molecule that is substantially shorter than the nucleic acid, wherein the recognition head of the signal molecule specifically binds to the affinity binding molecule and the electrically charged tail of the signal molecule brings a charge to the detection surface that is detected as taught by Eggers et al., in order to eliminate the exposure of the nucleic acids to radioactive elements, fluorescent dyes and other dangerous materials, and to greatly reduce the time and materials required for an assay.

With respect to claim 97, Sano et al. teach washing to remove any signal probe that is not specifically bound to the target immobilized in the reaction vessel (col. 8, lines 8-44).

Regarding claims 100, 102, 103, 105 and 108, Eggers et al. teach the recognition component binding directly to the target (Fig. 4; col. 7, lines 45-51) and the affinity binding molecule immobilized directly on the detection surface (Fig. 4; col. 7, lines 47-48), wherein the affinity binding molecule is a nucleic acid (col. 7, lines 48-50).

With respect to claims 112 and 115, Sano et al. teach the signal molecule comprising an RNA transcript (marker may be RNA and therefore the signal molecule comprises an RNA transcript, col. 5, lines 10-20) and Eggers et al. teach the nucleic acid having an RNA aptamer that specifically binds to the affinity binding molecule (DNA or RNA sequencing may be used, col. 3, lines 59-62; and sequence binds to affinity binding molecule, Fig. 4, col. 4, lines 49-62).

With respect to claims 117 and 119, Eggers et al. teach the entire target being a nucleic acid, therefore the recognition component and the electrically charged tail are nucleic acids (Fig. 4; col. 7, lines 40-51).

Regarding claim 118, Sano et al. teach the target being a nucleic acid (col. 3, line 49-col. 4, line 16).

With respect to claims 121 and 122, Eggers et al. teach the detection surface (assay substrate) being a semiconductor material that is silicon dioxide (col. 4, lines 40-48).

4. Claims 99, 109 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US 5,665,539) in view of Eggers et al. (US 5,532,128), as applied to claim 96, further in view of Israel et al. (US 2005/0064395).

Sano et al. in view of Eggers et al. teach immobilizing a recognition molecule directly to a detection surface, but differ from the instant claims by failing to teach a spacer molecule immobilized directly to the detection surface.

Israel et al. teach a detection surface having an immobilized recognition moiety and a spacer molecule (blocking agent) immobilized directly to the detection surface, wherein the spacer molecule is a polymeric organic molecule (par. 222), in order to block the surface where recognition molecules are not present.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to further include on the surface of Sano et al. in view of Eggers et al., a spacer molecule where the affinity binding molecule is not present as

taught by Israel et al., in order to guard against non-specific binding to the detection surface.

5. Claim 120 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US 5,665,539) in view of Eggers et al. (US 5,532,128), as applied to claim 119, further in view of Draper et al. (US 5,496,698).

Sano et al. in view of Eggers et al. teach a signal molecule having an electrically charged tail, but differ form the instant claims by failing to teach the electrically charged tail comprising a poly-A tail.

Draper et al. teach a nucleic acid strand having a poly(A) tail (col. 4, lines 23-39), in order to protect the nucleic acid.

Therefore it would have been obvious to one having ordinary skill in the art to use as the electrically charged tail in the method of Sano et al. in view of Eggers et al., a poly-A tail as taught by Draper et al., in order to provide a stabilizing structure to the signal molecule.

6. Claim 120 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sano et al. (US 5,665,539) in view of Tyvoll et al. (US 2004/0086870), as applied to claim 119, further in view of Draper et al. (US 5,496,698).

Sano et al. in view of Tyvoll et al. teach a signal molecule having an electrically charged tail, but differ form the instant claims by failing to teach the electrically charged tail comprising a poly-A tail.

Draper et al. teach a nucleic acid strand having a poly(A) tail (col. 4, lines 23-39), in order to protect the nucleic acid.

Therefore it would have been obvious to one having ordinary skill in the art to use as the electrically charged tail in the method of Sano et al. in view of Tyvoll et al., a poly-A tail as taught by Draper et al., in order to provide a stabilizing structure to the signal molecule.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641